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the Research Monitor

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Pharmacoepidemiology: Methods and Applications in Health Services Research

Michael L. Johnson, PhD



Michael L. Johnson, PhD

The study of the use of and the effects of drugs in large numbers of people is *pharmacoepidemiology*.¹ It is a relatively new applied field, bridging between clinical pharmacology, from which it derives its content and focus of inquiry, and epidemiology, from which it borrows its method of inquiry. The field primarily concerns itself with studies of adverse drug effects in individuals, and studies of adverse drug events in populations, performing comparisons in exposed vs. unexposed groups. Traditional major applications of the methods of pharmacoepidemiology are in the conduct of clinical trials, and even more so in the post-marketing surveillance of drugs. But the interests of pharmacoepidemiologists have broadened considerably in recent years into areas familiar to health services researchers, including: patient adherence; drug effectiveness and safety monitoring; cost-effectiveness; patterns of prescribing and dispensing; evaluation of pharmacological guidelines; drug utilization; and outcomes studies. Very large and well-linked inpatient and outpatient diagnosis claims, as well as laboratory and pharmacy record databases, are used to support all varieties of research designs in regulatory, marketing, legal and clinical domains.

The importance of this field to health services research in general and therefore to VHA is evident and

perhaps cannot be overstated. Recently, the Institute of Medicine published their report of a study commissioned by Congress of the VA National Formulary.² The report noted that prescription drug costs outpaced the growth of overall health care costs in the 1990s. Total prescription drug retail sales for 1999 were estimated at \$121.6 billion for 2.97 billion prescriptions, an increase of 18 percent from 1998. In the VHA, expenditures for pharmaceuticals were 11 percent of the total VHA budget in FY1999, almost \$2 billion of the \$17 billion total that year, and have been increasing from 11 to 21 percent annually in recent years. VHA is the largest single purchaser of pharmaceuticals in the U.S. Congress expressed four concerns: restrictiveness of the formulary; effect on quality of care; effect on costs; and comparison to other public and private-sector formularies. The National Formulary refers to the list of generic, brand name, and over-the-counter drugs, devices, and supplies maintained for use in the VA health care system. It also refers to the "formulary system" consisting of all measures that the VHA employs to choose, purchase, manage, negotiate prices and meet market share objectives of pharmaceuticals. The committee found that the National Formulary was not overly restrictive and "based on the scarce quality data available, that there was no reason to abandon the National Formulary." Furthermore, because a prescription drug benefit for over 39 million Medicare beneficiaries is being considered and politically debated, the committee recognized that the VA, as a national public system, would be a model upon which to base the Medicare formulary and benefit system. The committee called for "better data on quality issues in drug treatment and formulary operations with carefully designed and implemented health services research."

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Mission Statement

The Center impacts health and health care by conducting and translating outstanding research and by developing influential leaders in health outcomes, quality, access, utilization and costs.

Measurement Excellence Initiative (MEI) Web Site Developed

Kimberly J. O'Malley, PhD and Siddharta Reddy, MPH

The researcher's quest for the best instrument to measure an individual's health can be wrought with uncertainty and error. This is because it can be difficult to decide on an instrument when there are a variety of factors to consider, such as the large number of possible instruments, defining constructs, and difficulty in matching instruments to one's study needs.

The newly developed Measurement Excellence Initiative (MEI) web site:

[http://www. MeasurementExperts.org](http://www.MeasurementExperts.org)

aims to solve these and other problems for researchers. This VA Health Services Research and Development-funded initiative, housed within the Houston Center for Quality of Care and Utilization Studies, intends to carry out its mission through its web site. First, the site offers a place to disseminate information about finding, evaluating, and applying instruments. Second, MEI affords researchers educational opportunities in all phases of measurement methodology. Third, the organization allows this measurement knowledge to be shared freely among the research community. Lastly, MEI aims to advance measurement science through research.

Development of the MEI web site began in July, 2001, and the launch date for the web site was January 1, 2002. Initial emphasis was given to compiling and synthesizing instrument information previously published in electronic and book form and to developing the aspects of the web site that will facilitate researchers' education and sharing of information. Therefore, the sections of the web site that will be the furthest developed by launch date will include links and reviews of resources that currently exist for finding instrument information, educational aspects, and the message board. Whereas all aspects of the MEI will not be complete by launch date, the completed portions will provide researchers with easy access and a synthesis of currently available instrument information and a mechanism for researchers to receive measurement-related education and assistance.

The content organization of the web site was based on the goals from the MEI mission statement, therefore, sections on instrument information, educational opportunities, and information sharing aspects are found on the site. A menu along the left side allows for easy navigation. Located at the top of the menu is a link to the Site Map, which provides a clear overview of the site and its structure. Following the Site Map link is a Help link, which is intended to introduce and guide visitors through the web site's unique features, educate them about technical issues dealing with navigating efficiently, provide information about how to make the most of their visit, and most importantly, find the answers they seek. A link to the registration page is below the Help link. While registration with the site is not required for access, the benefits of doing so are twofold: first, registration allows users to receive the latest information about the site's development; and second, registration enables the user to have a profile that he or she can change as necessary. For example, users may update their educational accomplishments, changes in research interests, or modify contact information.

The next section entitled Find an Instrument is exactly what it proposes. Through its submenu, one can find potential instruments through other Internet sites or through book compendiums that contain numerous instruments in print. Both the Internet sites and books have been culled from hundreds of potentially useful sources and then reviewed to provide users with the most relevant sources of measurement tools and information. By collecting and assessing the current resources available to researchers, MEI may then take the next step in advancing measurement science.

The next two menu items are under development, but expected to be released later this year. The first of these is the Instrument Evaluation Recommendations. This section lists various factors that are generally used by researchers to gauge the appropriateness of an instrument for their work. It will also provide visitors with MEI's own suggestions for application of instruments to specific situations.

This section's construction will follow from MEI's panel of experts who will make recommendations for applying measurement criteria to instruments. The experts' recommendations will fall into two categories: first, an explanation of the nuances of applying measurement concepts such as reliability, validity, and responsiveness in different situations; and second, MEI will make recommendations about dealing with measurement issues, such as missing data, translation methods, and clinical significance.

The other section is the MEI Compendium, which will be a collection of instruments available directly from the MEI web site. The compendium will be the result of feedback gained from a survey of VA health services researchers regarding the constructs they measure. Based on this information, MEI will search the available literature to synthesize information on the instruments used to measure these constructs. This section will provide an efficient method for finding instruments and will eliminate users having to navigate through external web sites. This section will offer not only the instrument itself, but an evaluation of its usefulness in a context-sensitive manner, including any psychometric data available for the measure.

The Education Section is composed of seven subsections aimed at providing a foundation and refresher in the science of measurement. Measurement has many words in its jargon that confuse even the most seasoned scientist. The Terms and Topics section is a glossary of common words used throughout the site as well as on other sites related to measurement. In addition to vocabulary, this section also explains basic test theories in a clear lay terminology. Following the Terms and Topics is a section on books that cover psychometrics, measurement theory, health services research, general research methods, and other subjects, both broad and narrow in measurement scope. Books listed here have been reviewed to gauge their usefulness to health services researchers, among other criteria. The next section within education provides references and full text documents (in some cases) of classic papers in the fields of measurement, psychology and health services research. These papers date back to the early 1900s and illustrate the development of this field of science from its infancy to the impressive and essential status it now holds. The Classic Paper Section

provides an important reminder to those just entering health services research or measurement of the paradigm shifts that have taken place in the last century. The fourth section under Education is a link to a list of journals relevant to measurement, including psychometrics and psychology. Next, is the subsection entitled Measurement Sites, which is concerned with external Internet sites that provide educational content broadly related to measurement. The message board link follows, but it has its own link situated on the main menu for easy access and is described in detail below. Lastly, within the Education section is an FAQ, or frequently asked questions section, which answers researchers most common questions regarding measurement.

The message board is the link following Education and offers clinicians, researchers, students and anyone else interested in measurement the ability to post questions, spark lively debates, or launch ideas for specific forums within the science of measurement or health services research. The message board feature logs points for those who reply to questions. These points compose part of a registered user's profile and are used to rank that person according to their level of measurement knowledge. There are two ways to access the message board, either through the Education submenu or through its own link on the main menu.

Upcoming Events, the next item on the main menu, offers a simple way to find out about scheduled conferences, workshops, seminars, and other educational or developmental opportunities nationwide for people involved in measurement, psychology, and health services research. What is unique about this feature of the web site is that it offers an at-a-glance view of each month in one window frame while allowing a more detailed view of an individual month in the adjacent frame. The detailed frame shows a calendar of the chosen month with event dates highlighted while detailed descriptions of that month's events are provided below. Visitors may scroll ahead to see what is happening in the next several years.

The next link on the menu is the MEI Hall of Fame, which recognizes a diverse group of individuals who have made significant contributions to measurement and health services research. Every two months, the main page of the Hall of Fame will

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Feature Article

Cover Story

Pharmacoepidemiology

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Answering the Call

My own interests in pharmacy research derive mainly from my background as a biostatistician and my experience in large database analysis and risk-adjustment of health care outcomes. My first project in this area was a small contract with VISN 16 to study ways to develop measures of waste from computerized pharmacy records.³ My colleague Rebecca Beyth, MD, MPH and our project team linked dispensing and utilization records for 24,765 patients who had received Lansoprazole during FY1999. Lansoprazole was the highest cost drug to the VISN in that year, costing just over \$10 million. We created measures of gaps and overlaps in delivery, and found that patients who received their next refill more than 10 days earlier, or later than their next refill was due, had higher utilization of both inpatient and outpatient services. We determined the inventory of the drug in the possession of the patient, based on the assumption that the patient takes the drug as prescribed, and calculated the costs due to excess supply from overlaps, net after any gaps are taken out. We found that 8 percent of the total cost (almost \$800,000) was "wasted," due to overfilling.

Lessons learned from that project indicated that I needed better understanding of methodology using pharmacy databases, and I've been studying pharmacoepidemiology ever since. In a systematic

review of the literature, I've found many uses of large pharmacy databases and measures based on pharmacy data that are applicable to health services research. I will now briefly describe a few specific measures that can be created from pharmacy data, with application to studies of drug use, evaluation of pharmacological guidelines, drug safety and effectiveness, and outcomes research – the kind of research the IOM recommended – and then end by describing future plans to further "answer the call."

Measures of Comorbidity and Use

An interesting use of pharmacy records is the Chronic Disease Score (CDS), a measure of comorbidity developed by Von Korff and colleagues at the Center for Health Studies, Group Health Cooperative at Puget Sound.⁴ The CDS was validated by Richard Johnson and Mark Hornbrook from Kaiser Permanente Northwest, and refined by Daniel Clark from the Regenstrief Institute.⁵⁻⁶ The score is based on weights assigned to chronic disease classes, which are identified by medications or drug classes found in the dispensing record. For example, patients who are prescribed ACE inhibitors, or calcium channel blockers are assigned to the Hypertension group; loop diuretics are indicative of CHF; antilipemic agents such as statins indicate hyperlipidemia; and so on. A summary score is calculated based on the severity and number of disease classes. The score has been compared to other diagnostic based comorbidity measures, found to have similar predictive ability, and therefore is useful as an alternative or supplement to

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feature a new face from among the many that have established themselves in the relevant sciences. Along the side of the Hall of Fame page are thumbnail pictures and names of all the MEI Hall of Fame inductees. Clicking on one will bring up a larger picture, a biography, personal anecdotes or quotes, and selected article or book references that would be of interest to people in the field.

The next two links are about the Measurement Excellence Initiative itself and a place for visitors to share their opinions about the web site. The Who Are We? link provides a hierarchical structure of the MEI within the organizations that fund and house

its operations, as well as its affiliations. Furthermore, there is also background information on each person within the MEI team. The Feedback link is the final item on the menu. Here, users have a chance to provide MEI with questions, praise, and criticism on any subject associated with the web site. Based on the responses from a brief survey on the Feedback page, MEI can better serve its audience by learning what people in the field of measurement and health services research need and want to help them in their own research. In this way, the Measurement Excellence Initiative hopes to become an indispensable resource for the VA research community, as well as for the national health research community. **i**

the diagnostic-based measures. It would be interesting to compare the agreement of the pharmacy records with the diagnosis records in the identification of the patients with the comorbidities. Relatedly, studies have been conducted which demonstrate that pharmacy records can be used to identify patients with certain diseases as a means to establish a patient population for study.

Many studies describe pharmacy use, but what exactly is meant by “use” can actually differ quite a bit from study to study. For example, use is often measured in terms of prevalence, i.e., how many patients are using a certain drug at a given time, or it can be described in terms of incident use in patients newly diagnosed and treated during a time period. Measures of use are closely related to the dose prescribed and taken by the patient. Pharmaco-epidemiologists are careful to describe use not only in terms of proportions of patients on a drug but also the dosage levels used. Dose is needed to quantify exposure when the drug is being considered as a possible risk factor for adverse events. Because automated databases only contain information on filled prescriptions and not on the actual duration and timing of the drug intake by the study group, for risk-assessment purposes, dosage information in the computerized records can be calculated to obtain exposure levels, if the assumption is made that patients take the drug exactly as prescribed. Otherwise, a number of days of exposure must be assigned to each prescription, a method that is referred to as a “time-window” design. In this method, the number of cases of adverse events that occurs within the time-window is collected, and the total time covered by the time-windows is estimated as the time at risk in the exposed group. Determination of the correct time-window can depend on the drug and patient characteristics, such as age or gender, and can influence associations with events, so that careful classification of the time-window is essential for unbiased findings.

A common measure of pharmacy use is the Medication Possession Ratio, or MPR. Stroupe and colleagues from the Midwest Center for Health Services and Policy Research used the MPR to examine the relationship between medication supplies and costs in 12 major categories of drugs used to treat chronic diseases.⁷ The MPR is based on the time interval between refills. For example, if the number of days

until the next refill is expected to be 10 days, and the patient actually obtains the next refill on the 10th day, then the MPR = 1.0. If the patient obtains the refill 5 days early, the MPR is 2.0 (10 expected days/5 actual days), which indicates that the patient has twice the supply necessary. If the patient obtained the refill 10 days later than expected, the MPR is 0.5 (10/20) indicating that the patient had only half the supply necessary for the time period. We chose not to use the MPR in our study of Lansoprazole because the ratio is dependent on the days supply, and the interpretation varies depending on the proportion of use over differing durations. We chose to focus on the actual supply in possession by calculating the exact inventory, again, based on the assumption that the patient takes the drug as prescribed.

Future Plans

VHA aggregates all pharmacy dispensing records for the approximately 3.7 million veterans who receive health care in the VA at the Pharmacy Benefits Management (PBM) group in Hines, Illinois, and this database is accessible for researchers. The dispensing records can be linked to the inpatient and outpatient utilization records at the Austin Automation Center, for projects examining pharmacy use with other healthcare utilization or outcomes. With colleagues here in the Center, we are developing two grant applications proposing to use the pharmacy data. The first is a project planned with Anita Deswal, MD, a cardiologist in the Center and member of the CHF QUERI team. We are hoping to obtain funding to analyze the pharmacy records for a national cohort of over 300,000 patients with heart failure. The cohort was created as part of the CHF QUERI, and contains measures of inpatient and outpatient utilization and outcomes, such as readmission, multi-stay hospitalization rate, urgent clinic visit rates, and survival. We hypothesize that patterns of use of heart failure medications vary and will be associated with both utilization and outcomes. Another project is being planned with Robert Morgan, PhD, and seeks to examine the use of VA pharmacy services by veterans enrolled in Medicare + Choice (M+C) managed care plans. Co-utilization of Medicare fee for service care and the VA is well-documented, but less is known about the impact of M+C plans on VA use. In particular, some plans have pharmacy benefits, while others do not. We hypothesize that use of VA pharmacy services by Medicare-enrolled veterans

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Cover Story

New Research Grants

Title: "Understanding Ethnic Variations in Physician-Patient Communications" (*VA HSR&D Research Career Development Award*)

PI: **Paul Haidet, MD, MPH**

Dates of Support: 7/1/01-6/30/04

Most of the literature to date on racial variations in care has only identified the problem by examining outcomes. Dr. Haidet's research will contribute to a solution by identifying critical variations in health care processes (i.e., physician-patient communication) that are remediable, and will continue the VHA tradition of improving the health quality of all US citizens through leading research. Dr. Haidet's career development award will lay the groundwork toward designing interventions to improve the communication between physicians and patients of all races and ethnicity.

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Title: "Understanding and Eliminating Racial/Ethnic Variations in Health Care" (*VA HSR&D Advanced Research Career Development Award*)

PI: **Howard Gordon, MD**

Dates of Support: 7/1/01-6/30/04

Dr. Gordon's methods used in his study are designed to assess the relationship of race and doctor-patient communication. He will apply communication theories to the study of communication and race and, if indicated, to the design of interventions. The hypotheses he will investigate include: H₁: Patients receive different care when communication of recommendations varies by race/ethnicity of the interactants; H₂: Doctors and patients who differ by race/ethnicity have more difficulty communicating; H₃: Doctors and patients who differ by race/ethnicity are more likely to have differing perceptions of the effectiveness of communication and interpersonal factors, and these perceptions influence participation in decision making, adherence/acceptance of recommendations, trust and satisfaction; H₄: Patients' racial, ethnic and cultural belief systems influence their perceptions of disease and treatment; and H₅: Patients and doctors can learn to communicate more effectively. Assessment of potential racial/

ethnic variation in both actual and perceived communication is important because it is possible that variation occurs in both or only in one. Occurrence in only one would indicate a need for focused intervention while occurrence in both would indicate a need for a wider spectrum of interventions. In addition, association with outcomes and other perceptions will aid in the understanding of potential racial variation in communication.

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Title: "Variation in Office-Based Treatment of Opiate Abuse" (*AHRQ Minority Supplement Grant*)

PI: **Carol Ashton, MD, MPH**

Project Leader: **Herminia Palacio, MD, MPH**

Dates of Support: 9/1/01-8/31/05

The 4-year project will focus on evaluating racial and ethnic variations in the impact of the Drug Addiction Treatment Act of 2000 in enabling physicians to dispense Schedule III, IV or V drugs for maintenance or detoxification treatment of opiate-addicted patients. There are 3 main project components: 1) a community partnership-building and policy analysis component; 2) an epidemiologic component involving secondary data analysis of existing public access databases to estimate prevalence of heroin use in Houston; and 3) a health services research component involving primary data collection through focus groups and surveys.

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Title: "Treatment of Depression in Patients with PTSD" (*VA HSR&D Service Directed Research Grant*)

PI: **Nancy Jo Dunn, PhD**

Dates of Support: 10/1/01-9/30/02

The 1-year extension in funding to the original grant will allow Dr. Dunn the opportunity to complete all follow-up assessments on the male sample and to conduct a pilot study with a 6-month follow up on the female sample. The original grant was funded for 4 years in 1997. The grant is a randomized, controlled trial comparing the clinical efficacy and cost-effectiveness of Self-Management Therapy versus Psycho-educational Group Therapy in male and female veterans who have concurrent PTSD and clinical depression.

Title: "Causes and Consequences of Aggressive Behavior in Demented Patients" (VA HSR&D Investigator Initiated Research Grant)

PI: **Mark Kunik, MD, MPH**

Dates of Support: 1/1/01-12/31/06

Although several risk factors and consequences of aggressive behavior in patients with dementia have been identified, the causal relationship between aggression and its putative precipitants or consequences has not been determined, thus limiting the ability to design effective interventions to reduce aggression and modify its potentially devastating impact. In this project, Dr. Kunik's aims are to: 1) determine the incidence of aggressive behavior in an inception cohort of adults recently diagnosed with dementia; 2) determine the antecedents of aggressive behavior in an inception cohort of adults recently diagnosed with dementia; 3) determine the effects and consequences of aggressive behavior on patients caregivers, and the health care system; and 4) use the information derived from achieving the first two aims to develop a health risk appraisal (HRA) intervention to assess and address risk factors for aggression to prevent the development of aggression and its adverse consequences. This study's innovative HRA, developed through quantitative and qualitative methods, has the potential to shift the emphasis in these cases from treatments linked inexorably to loss of quality of life to one on prevention, early detection and intervention, and improved use of health care system resources.

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Title: "Improvement in Quality of Care of Demented Nursing Home Residents: Pain Management Approaches" (VA HSR&D Research Career Development Award)

PI: **A. Lynn Snow, PhD**

Dates of Support: 7/1/02-6/30/05

Dr. Snow's projects were planned with the purpose of building the necessary components for a successful nursing home pain management tracking system. They are: 1) appropriate assessment tools; 2) an understanding of the potential barriers to a pain management and tracking system, and valid responses to these potential barriers; and 3) an understanding of how best to utilize all the

different sources of pain assessment and treatment information available in the nursing home system. She will then develop and evaluate such a pain management and tracking system. Dr. Snow's research will strongly impact VHA patient care because: long term care is a significant VHA cost; the prevalence of dementia in long term care facilities is high; the prevalence of dementia in the veteran population is high and is increasing; and the VHA has identified pain control as a priority clinical and research area.

In Press

Hashem B. El-Serag, MD, MPH; Nadine R. Bailey, MS; Mark Gilger, MD; **Linda Rabeneck, MD, MPH**, "Endoscopic Manifestations of Gastroesophageal Reflux Disease in Patients Between 18 months and 25 years without Neurological Deficits," *American Journal of Gastroenterology*, 2002.

Background. The aim of this study was to determine the prevalence of erosive esophagitis and Barrett's esophagus (BE) among a large cohort of neurologically normal children with gastroesophageal reflux disease (GERD).

Conclusions. Manifestations of severe disease such as erosive esophagitis were present in more than one third of patients in a large cohort of neurologically normal children with GERD who underwent endoscopy. Further studies are needed to examine the future subsequent clinical course of these children. On the other hand, BE was absent making it likely that the duration of reflux is a major risk factor for BE.

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Laura A. Petersen, MD, MPH; Steven M. Wright, PhD; Eric D. Petersen, MD, MPH; Jennifer Daley, MD, "Impact of Race on Cardiac Care and Outcomes in Veterans with Acute Myocardial Infarction," *Medical Care*, 2002.

Objectives. The goal of this study was to assess racial differences in process of care and outcome for acute myocardial infarction in the VA health care system.

Conclusions. In this integrated health care system, we found no significant racial disparities in use of

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non-interventional therapies, diagnostic coronary angiography, or short- or long-term modality. Disparities in use of thrombolytic therapy and coronary artery bypass surgery existed, however, even after accounting for differences in clinical indications for treatment and patient refusals. Further work should assess the role of the medical interaction and physician behavior in racial disparities in use of health care.

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Monir Hossain, MS; Steven M. Wright, PhD; **Laura A. Petersen, MD, MPH**, "Comparing Performance of Multinomial Logistic Regression and Discriminant Analysis for Monitoring Access to Care for Acute Myocardial Infarction," *Journal of Clinical Epidemiology*, 2002.

Objective. One way to monitor patient access to emergent health care services is to use patient characteristics to predict arrival time at the hospital after onset of symptoms. This predicted arrival time can then be compared to actual arrival time to allow monitoring of access to services. Predicted arrival time could also be used to estimate potential effects of changes in health care service availability, such as closure of an emergency department or an acute care hospital. Our goal was to determine the best statistical method for prediction of arrival intervals for patients with acute myocardial infarction (AMI) symptoms. We compared the performance of multinomial logistic regression (MLR) and discriminant analysis (DA) models.

Conclusions. The choice of MLR or DA with proportional priors, or DA with equal priors for monitoring time intervals of predicted hospital arrival time for a population should depend upon the consequences of misclassification errors.

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Linda Rabeneck, MD, MPH; Kimberly Wristers, PhD; Jay Goldstein, MD; Glenn Eisen, MD, MPH; Seema D. Dedhiya, MS; Thomas A. Burke, PharmD, "Reliability, Validity and Responsiveness of Severity of Dyspepsia Assessment (SODA) in a Randomized Clinical Trial of Cox-2 Specific Inhibitor and Traditional NSAID Therapy," *American Journal of Gastroenterology*, 2002.

Objectives. To assess the Severity of Dyspepsia

Assessment (SODA) scales as measures of change in dyspepsia-related health in a blinded randomized controlled trial in arthritis patients treated with non-steroidal anti-inflammatory drugs (NSAIDs).

Conclusions. SODA is a reliable, valid instrument for use as a measure of dyspepsia tolerability in future clinical trials involving Cox-2 specific and/or traditional NSAIDs.

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Linda Rabeneck, MD, MPH; Kimberly Wristers, PhD; Catherine Campbell, MD; **Julianne Soucek, PhD; Terri Menke, PhD; Nelda P. Wray, MD, MPH**, "Sociodemographics, General Health and Psychologic Health in Uninvestigated Dyspepsia: A Comparison of Public and Private Patients," *Journal of Clinical Gastroenterology*, 2002.

Goals. To compare the dyspepsia severity, general health and psychologic health of patients with uninvestigated dyspepsia presenting in private and public settings.

Conclusions. Burden of illness and psychologic factors such as patient expectations, are known to have important effects on patient outcomes. Striking differences in these factors exists in patients with uninvestigated dyspepsia seen in private and public settings. In the future, we need to take these factors into account, both in conducting studies in dyspepsia and in interpreting the results for different practice settings.

Recent Publications

Hashem B. El-Serag, MD, MPH; Mark Gilger, MD; **Mark Kuebel, MS; Linda Rabeneck, MD, MPH**, "Extra-esophageal Associations of Gastroesophageal Reflux Disease in Children without Neurological Defects: A Case-Control Study," *Gastroenterology*, 2001; 121:1294-1299.

Background. The potential association between gastroesophageal reflux disease (GERD) and extra-esophageal manifestations remains unknown in children without neurological defects. We conducted a large case-control study to examine the association between GERD and several upper and lower respiratory disorders in these children.

Conclusions. GERD in children without neurological defects is associated with a several-fold increase in the risk of sinusitis, laryngitis, asthma, pneumonia and bronchiectasis. Further studies are needed to examine whether a cause-effect relationship exists between GERD and these disorders in children.

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Hashem B. El-Serag, MD, MPH; Peter A. Richardson, PhD; James E. Everhart, MD, MPH, "The Role of Diabetes in Hepatocellular Carcinoma: A Case-Control Study Among United States Veterans," *American Journal of Gastroenterology*, 2001; 96:2462-2467.

Objective. Diabetes mellitus (DM) has been reported to increase the risk of hepatocellular carcinoma (HCC). We carried out a case-control study to examine the role of DM while controlling for several known risk factors of HCC.

Conclusions. DM increased the risk of primary liver cancer (PLC) only in the presence of other risk factors such as hepatitis C or B or alcoholic cirrhosis. Hepatitis C infection and alcoholic cirrhosis account for most of PLC among veterans.

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Michael L. Johnson, PhD; Howard S. Gordon, MD; Nancy J. Petersen, PhD; Nelda P. Wray, MD, MPH; A. Laurie Shroyer, PhD; Frederick L. Grover, MD; Jane M. Geraci, MD, MPH, "Effect of Definition of Mortality on Hospital Profiles," *Medical Care*, January 2002.

Background. Hospitals are ranked based on risk-adjusted measures of post-operative mortality, but definitions differ as to which deaths following surgery should be included.

Objective. To determine whether varying the case definition of the deaths following surgery that are included in assessing the quality of coronary artery bypass surgery affects the identification of outlier hospitals.

Conclusions. Judgments regarding the quality of a hospital's performance of coronary artery bypass surgery vary depending on the definition of post-operative mortality that is used. Further research is needed to assess what definition is most appropriate

to identify quality of care problems.

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Laura A. Petersen, MD, MPH; Sharon-Lise T. Normand, PhD; Lucian L. Leape, MD; Barbara J. McNeil, MD, PhD, "Comparison of Use of Medications After Acute Myocardial Infarction in the Veterans Health Administration and Medicare," *Circulation*, December 11, 2001.

Background. There is concern that care provided in the Veterans Health Administration (VA) may be of poorer quality than non-VA health care. We compared use of medications after acute myocardial infarction in the VA to that in non-VA health care settings under fee-for-service (FFS) Medicare financing.

Conclusions. Ideal candidates in VA were at least as likely as those in FFS to receive medical therapies of known benefit for acute myocardial infarction.

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varies by level of M+C enrollment and by the presence and extent of a pharmacy benefit in the M+C plans. Because market penetration of managed care plans varies and changes in different parts of the country, we expect that pharmacy use in the VA may vary geographically in part due to M+C plan availability in different regions.

Pharmacoepidemiology is a very interesting field, with many applications of importance to the VA, and health services research. I wish to thank my colleagues here at the Center, and especially my mentors, Carol Ashton, MD, MPH and Nelda P. Wray, MD, MPH, for the opportunity to learn about and contribute to addressing the many questions of critical importance in the quality and outcomes of pharmaceutical care.

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1. Pharmacoepidemiology, 3rd edition. Strom BL, ed. John Wiley & Sons Ltd., New York, NY. 2000.
2. Description and Analysis of the VA National Formulary, Blumenthal D and Herdman R, eds. Institute of Medicine, Division of Health Care Services. National Academy Press, Washington, DC. 2000.

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Staff News

Fall 2001

HSR&D Impacts 2001, a VA Health Services Research & Development Service publication showcased studies by HCQCUS senior scientists, **Dr. Carol Ashton**, **Dr. Tracie Collins**, **Dr. Laura Petersen**, **Dr. Terri Menke**, **Dr. Nancy Petersen**, **Dr. Julie Soucek**, and **Dr. Nelda Wray**. In the publication's forward, Dr. John Demakis, HSR&D Service Director, stated that these studies "highlight HSR&D's contribution to VA's goal of improving the service, efficiency and access to high quality of care for every veteran."

Houston Texas Healthcare reported in its October 2001 issue that **Baruch Brody, MD**, HCQCUS Affiliate Scientist and the Leon Jaworski Professor of Biomedical Ethics and the director of the Center for Medical Ethics and Health Policy (a joint program at Baylor College of Medicine and Rice University) "has been elected to the Institute of Medicine, a world-renowned institution devoted to advancing scientific knowledge to improve human health."

November

Tracie Collins, MD, MPH, HCQCUS Senior Scientist, was interviewed by *Reader's Digest* about peripheral arterial disease (PAD). Dr. Collins viewed this as a perfect opportunity to get information about PAD out to the lay public and to reinforce the new HCQCUS initiative that focuses on designing studies and presenting research results that truly "make a difference."

Anita Deswal, MD, HCQCUS Senior Scientist, was interviewed by the *Houston Chronicle* regarding the study she presented at the American Heart Association's annual meeting on November 14 in Anaheim, Calif. The article, printed in the November 15 issue of the *Chronicle*, pointed out "that contrary to conventional wisdom, blacks actually die of heart failure at a lesser rate than whites — as long as the quality of care is the same." "The study of Veterans Affairs hospital patients nationwide also found that blacks subsequently used hospital emergency-room and urgent-care facilities more frequently than their white counterparts, who were more likely to receive comprehensive outpatient care."

Hashem El-Serag, MD, MPH, HCQCUS Senior Scientist, was a visiting professor at the University of Arizona Medical Center at Tucson in November.

Michael Johnson, PhD, HCQCUS Associate Director, presented the seminar, "Pharmacy Waste, Cost, and Healthcare Utilization: A Study of Lansoprazole" at the Center for Pharmacoeconomic Studies at the University of Texas in Austin on November 14.

Laura Petersen, MD, MPH, HCQCUS Senior Scientist, was awarded the "Best Poster on an Acute Care Topic" at the Second Annual Kelsey Research Foundation Houston Area Health Services and Outcomes Research Conference on November 15. Dr. Petersen was also featured in the fall issue of the Baylor *Department of Medicine* newsletter which highlighted her SGIM Award as Investigator of the Year. In addition, the newsletter featured an article on the HCQCUS Open House in August.

Linda Rabeneck, MD, MPH, HCQCUS Senior Scientist, was a visiting professor at the University of Western Ontario, London, Ontario, Canada, November 7-8.

A study based on the Master's thesis of **Siddharta Reddy, MPH**, HCQCUS Project Staff, was published in the December 2001 issue of the *American Journal of Infection Control*. The purpose of Mr. Reddy's study was to determine the efficacy of engineering controls in reducing the sharps injury rate among healthcare workers in a large metropolitan hospital in Texas.

2002

Hashem El-Serag, MD, MPH, HCQCUS Senior Scientist, was the keynote speaker for the American College of Physicians, Colorado Chapter, Scientific Meeting in January 2002. Dr. El-Serag's address was titled, "Hepatocellular Carcinoma: An Impending Epidemic."

Carol Ashton, MD, MPH, HCQCUS Director has announced that **Lisa Rubenstein, MD, MSPH**, Director of the HSR&D Center in Sepulveda, has agreed to come to our Center as a visiting professor in 2002. Dr. Rubenstein was the recipient of last year's VA Under Secretary Award for Outstanding Achievement in Health Services Research and is a highly esteemed researcher in quality assessment, among other subjects.

Pharmacoepidemiology*(Continued from Page 9)*

3. Johnson ML, Beyth R, Richardson P and Yu H. Lansoprazole pharmacy project final report – VISN 16. *HCQCUS Technical Report* 00-03.
4. Von Korff M, Wagner EH and Saunders K. A chronic disease score from automated pharmacy data. *J Clin Epi*, 45(2), 197-203, 1992.
5. Johnson RE, Hornbrook MC and Nichols GA. Replicating the chronic disease score (CDS) from automated pharmacy data. *J Clin Epi*, 47(10), 1191-1199, 1994.
6. Clark DO, Von Korff M, Saunders K, Baluch WM and Simon GE. A chronic disease score with empirically derived weights. *Medical Care*, 33(8), 783-795, 1995.
7. Stroupe KT, Murray MD, Stump TE and Callahan CM. Association between medication supplies and healthcare costs in older adults from an urban healthcare system. *JAGS*, 48:760-768, 2000. **i**

Community-Based Participatory Research

Herminia Palacio, MD, MPH

The Community Liaison Team, one of six teams established as part of the Research Excellence Initiative, is exploring new territory for the Center and an area of emerging importance to health services research. Unlike the traditional database research method, community-based participatory research seeks to actively involve the community throughout the research process, including having community members influence the research agenda. The goals of the team are to educate the Center's faculty about this method and how it is amenable to research questions and designs, and to engage the Center in discussion about the potential role community-based participatory research might play in the Center's future research endeavors.

As a kickoff to these discussions, the team will present at the QOWW conference on March 27 (*see QOWW schedule on back cover*). The Community Liaison Team's current members are Jessica Davila, Nancy Jo Dunn, Paul Haidet, Herminia Palacio, Linda Stelljes, Julianne Soucek, Anh Tran, Mary York, and UT School of Public Health intern, Tracy Urech, who not only staffs the committee, but makes insightful contributions to team discussions.

New Staff

Abeer Alsarraj, BS Project Staff
 Junaia Carter, BS Project Staff
 Serena Chu, PhD Post-doctoral Fellow
 Jessica Davila, PhD Post-doctoral Fellow
 Dianna Densmore, MS Chief of Project Staff
 Regina Drake, AAS Administrative Staff
 Lauren Elissa, MPH Project Staff
 Marvella Ford, PhD Senior Scientist
 Theresa Foss, BS Human Resource Manager
 Thomas Giordano, MD Senior Scientist
 April Hernandez Administrative Staff
 Lindsay Hommel, BS Administrative Staff
 P. Adam Kelly, PhD, MBA Senior Scientist
 Robert Mooney Administrative Staff
 Pauline O'Reilly Project Staff
 Emiel Ownes, EdD Programming Staff
 Herminia Palacio, MD, MPH Senior Scientist
 Diana Urbauer, MS Programming Staff
 Tracy Urech, BA Administrative Staff
 Mary York, PhD Senior Scientist

Promotions

Ken Pietz, PhD Senior Scientist
formerly Programming Staff

Appointments

A. Lynn Snow, PhD HCQCUS
 Director of Education

**Welcome and
 Congratulations!**

Staff News

Senior Scientists:

Carol M. Ashton, MD, MPH

Rebecca J. Beyth, MD, MS

Ursula K. Braun, MD

Tracie C. Collins, MD, MPH

Anita Deswal, MD

Nancy Jo Dunn, PhD

Hashem B. El-Serag, MD, MPH

Marvella Ford, PhD

Thomas Giordano, MD

Laura Goetzl, MD, MPH

Howard S. Gordon, MD

Paul M. Haidet, MD, MPH

Michael L. Johnson, PhD

P. Adam Kelly, PhD, MBA

Mark E. Kunik, MD, MPH

Kimberly J. O'Malley, PhD

Terri J. Menke, PhD

Robert O. Morgan, PhD

Herminia Palacio, MD, MPH

Laura A. Petersen, MD, MPH

Nancy J. Petersen, PhD

Ken Pietz, PhD

Linda Rabeneck, MD, MPH

A. Lynn Snow, PhD

Julianne Soucek, PhD

Maria Suarez-Almazor, MD, PhD

Nelda P. Wray, MD, MPH

Mary J. York, PhD

HCQCUS Seminar Series 2002

- Feb 20 **Rebecca Beyth, MD, MS**
"Project Management"
- Mar 6 **Carol Ashton, MD, MPH**
"Mentoring"
- Mar 20 **Andrew Schafer, MD**
"Funding: Baylor and VA Perspectives"
- Apr 3 **Angelita Vinluan, CPA**
Shannon Dwyer, BS
"Managing a Project Budget"
- Apr 17 **Alvin Tarlov, MD**
REI Community Liaison Team
"Social Determinants of Health"

HCQCUS New Faculty and Post-doctoral Seminars

- Feb 21 **Nancy Petersen, PhD**
Michael Johnson, PhD
"VA/Non-VA Databases"
- Feb 28 **Kimberly O'Malley, PhD**
"Psychometric Basics"

QOWW Research in Progress Conference Schedule

- Feb 27 **Michael Johnson, PhD**
"Pharmacoepidemiology: Methods and Applications in Health Services Research"
- Mar 13 **Maria Suarez-Almazor, MD, PhD**
"Determining Patient Preferences Using Conjoint Analyses"
- Mar 27 **REI Community Liaison Team***
"Community-Based Participatory Research: Conceptual Framework and Examples from the Field"
- *(see list of Community Liaison team members in article on page 11)*
- Apr 10 **Anita Deswal, MD**
"Racial Differences in Health Care Utilization and Outcomes in Veterans with CHF"



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